

provision must contain the elements in paragraphs (i)(1) and (i)(2) of this section.

(j) *Who, within FDA, can approve issuance of guidance documents?* Each center and office must have written procedures for the approval of guidance documents. Those procedures must ensure that issuance of all documents is approved by appropriate senior FDA officials.

(k) *How will FDA review and revise existing guidance documents?*

(1) The agency will periodically review existing guidance documents to determine whether they need to be changed or withdrawn.

(2) When significant changes are made to the statute or regulations, the agency will review and, if appropriate, revise guidance documents relating to that changed statute or regulation.

(3) As discussed in paragraph (f)(3) of this section, you may at any time suggest that FDA revise a guidance document.

(l) *How will FDA ensure that FDA staff are following GGP's?*

(1) All current and new FDA employees involved in the development, issuance, or application of guidance documents will be trained regarding the agency's GGP's.

(2) FDA centers and offices will monitor the development and issuance of guidance documents to ensure that GGP's are being followed.

(m) *How can you get copies of FDA's guidance documents?* FDA will make copies available in hard copy and, as feasible, through the Internet.

(n) *How will FDA keep you informed of the guidance documents that are available?*

(1) FDA will maintain on the Internet a current list of all guidance documents. New documents will be added to this list within 30 days of issuance.

(2) Once a year, FDA will publish in the FEDERAL REGISTER its comprehensive list of guidance documents. The comprehensive list will identify documents that have been added to the list or withdrawn from the list since the previous comprehensive list.

(3) FDA's guidance document lists will include the name of the guidance document, issuance and revision dates,

and information on how to obtain copies of the document.

(o) What can you do if you believe that someone at FDA is not following these GGP's? If you believe that someone at FDA did not follow the procedures in this section or that someone at FDA treated a guidance document as a binding requirement, you should contact that person's supervisor in the center or office that issued the guidance document. If the issue cannot be resolved, you should contact the next highest supervisor. You can also contact the center or office ombudsman for assistance in resolving the issue. If you are unable to resolve the issue at the center or office level or if you feel that you are not making progress by going through the chain of command, you may ask the Office of the Chief Mediator and Ombudsman to become involved.

[65 FR 56477, Sept. 19, 2000]

### Subpart C—Electronic Media Coverage of Public Administrative Proceedings; Guideline on Policy and Procedures

SOURCE: 49 FR 14726, Apr. 13, 1984, unless otherwise noted.

#### § 10.200 Scope.

This guideline describes FDA's policy and procedures applicable to electronic media coverage of agency public administrative proceedings. It is a guideline intended to clarify and explain FDA's policy on the presence and operation of electronic recording equipment at such proceedings and to assure uniform and consistent application of practices and procedures throughout the agency.

#### § 10.203 Definitions.

(a) *Public administrative proceeding* as used in this guideline means any FDA proceeding which the public has a right to attend. This includes a formal evidentiary public hearing as set forth in part 12, a public hearing before a Public Board of Inquiry as set forth in part 13, a public hearing before a Public Advisory Committee as set forth in part